To: 'ebelilos@ofwlaw.com'[ebelilos@ofwlaw.com]
Cc: McQueen, Jacqueline[McQueen.Jacqueline@epa.gov]; Richardson, Tony (CDC/OD/OADS)[lmr7@cdc.gov]
From: Zirger, Jeffrey (CDC/OD/OADS)
Sent: Mon 4/11/2016 11:46:47 AM
Subject: CDC Documents requested for ATSDR-2016-0002
Att4c_Facility Eligibility Scrning clean 20160210.docx
Att4f_Field Sampling Collection Form clean 20160210.docx
Att5c_Facility User Eligibility Screening clean 20160210.docx
Att5f_Full Exposure Characterization Form clean 20160210.docx
SSA_Synthetic Turf clean 20160224.docx
SSB_Synthetic Turf clean 20160224.docx

Good morning, Mr. Belilos. I have been asked to provide you with a number of documents associated with the Collections Related to Synthetic Turf Fields with Crumb Rubber Infill ICR (ATSDR-2016-0002). Please find attached, Supporting Statements A and B, as well as the Information Collection Instruments. Let me know if there are any additional documents requested and I will make them available.

Regards,

Jeffrey M. Zirger, Ph.D.

HEALTH SCIENTIST

Centers for Disease Control and Prevention (CDC)

Office of the Director

Office of the Associate Director for Science

Office of Scientific Integrity

1600 Clifton Road, NE MS D-74

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[redacted]

Fax: (404) 639-3249

Form Approved
OMB No. 0923-XXXX
Exp. Date xx/xx/20xx
xxxxxx/xx/xx/20xx

Attachment 4c. Facility Eligibility Screening

Caller: May I speak to [NAME OF Facility Owner/Operator]? A few weeks ago, you should have received a recruitment letter describing a new study on facilities using synthetic turf fields with crumb rubber infill. I am _____ from the Agency for Toxic Substances and Disease Registry (ATSDR), and I am calling you to determine your willingness to participate in this federally funded study being conducted with the United States Environmental Protection Agency (U.S. EPA). Are you interested in participating in a short 5 minute survey to find out if you can participate in this project?

Facility owner/operator is not interested in the project:
Facility Owner/Operator: No, I am not interested at this time.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Facility owner/operator is interested in the project:
Facility owner/operator: Yes, I would like to learn more.
Caller: To find out if you are eligible I will read the questions to you over the phone. If you are ready I'm going to read you a few questions.

1. Do you currently own a facility with synthetic turf fields? ..... ☐
2. Do you currently operate a facility with synthetic turf fields? ..... ☐
   If both #1 and #2 are no respondent is ineligible.
   Caller: You did not answer "Yes" to either question so you are not eligible to participate in this project. I am sorry. Thank you for your time.
   END CALL.

   If #1 and/or #2 are yes:
3. Would you be willing to be enrolled in this new study about facilities like yours that use and maintain of synthetic turf fields with crumb rubber infill? ..... ☐
   If no, respondent is a refusal.
   Caller: Ok, thank you for your time and have a good day.
   END CALL.

If #3 is yes:
In order to help us determine if your facility is eligible, we have some additional questions specific to your facility:

4. Are there outdoor synthetic turf fields with crumb rubber infill at your facility?..... ☐
   If no, skip to question #8.

   If yes:
5. How many outdoor synthetic turf fields are present at your facilities?....._____
6. What was the installation date(s)?....._____
7. What was the date of the most recent tire crumb replenishment?....._____

8. Are there indoor synthetic turf fields with crumb rubber infill at your facility?..... ☐
   If no, skip to question #12.

   If yes:
9. How many indoor synthetic turf fields are present at your facilities?....._____
10. What was the installation date(s)?....._____
11. What was the date of the most recent tire crumb replenishment?....._____

12. Are there natural grass fields present at your facility? ..... ☐
13. In addition to a short survey, would you be willing to provide samples of crumb rubber infill from the different synthetic turf fields at your facility? You will have the option of collecting the samples yourself, or allowing one of our trained study staff to do that for you. ..... ☐

If #3 and #4 or #5 are yes: Facility owner/operator is eligible and willing to participate
Caller: Thank you for being willing to take a survey and to provide samples of crumb rubber infill. You are eligible to participate in this project. Would you like to schedule an appointment?
..... ☐

Facility owner/operator is not interested in scheduling an appointment immediately:
Facility Owner/Operator: No, I do not have time at the moment.
Caller: OK, I will call at a better time to schedule an appointment. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Facility owner/operator is interested in scheduling an appointment immediately:
Facility owner/operator: Yes, I am interested in scheduling an appointment now.
Caller: OK, I have you scheduled for ----------. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Form Approved
OMB No. 0923-XXXX
Exp. Date xx/xx/20xx

Attachment 4f. Field Sampling Collection Form
[NOTE: tentative pending on study design completion and method availability]

Study ID Number _____

Sample Collection Date _____

Collector ID _____

Crumb Rubber Samples Collection – For Metals (Plastic Containers)

Field Location	Sample Collected
S1	Yes No
S2	Yes No
S3	Yes No
S4	Yes No
S5	Yes No
S6	Yes No
S7	Yes No

Crumb Rubber Samples Collection – For Organics (Glass Containers)

Field Location	Sample Collected
S1	Yes No
S2	Yes No
S3	Yes No
S4	Yes No
S5	Yes No
S6	Yes No
S7	Yes No

Crumb Rubber Samples Collection – For Microbes (Sterile Plastic Containers)

Field Location	Sample Collected
S1	Yes No
S2	Yes No
S3	Yes No
S4	Yes No
S5	Yes No
S6	Yes No
S7	Yes No

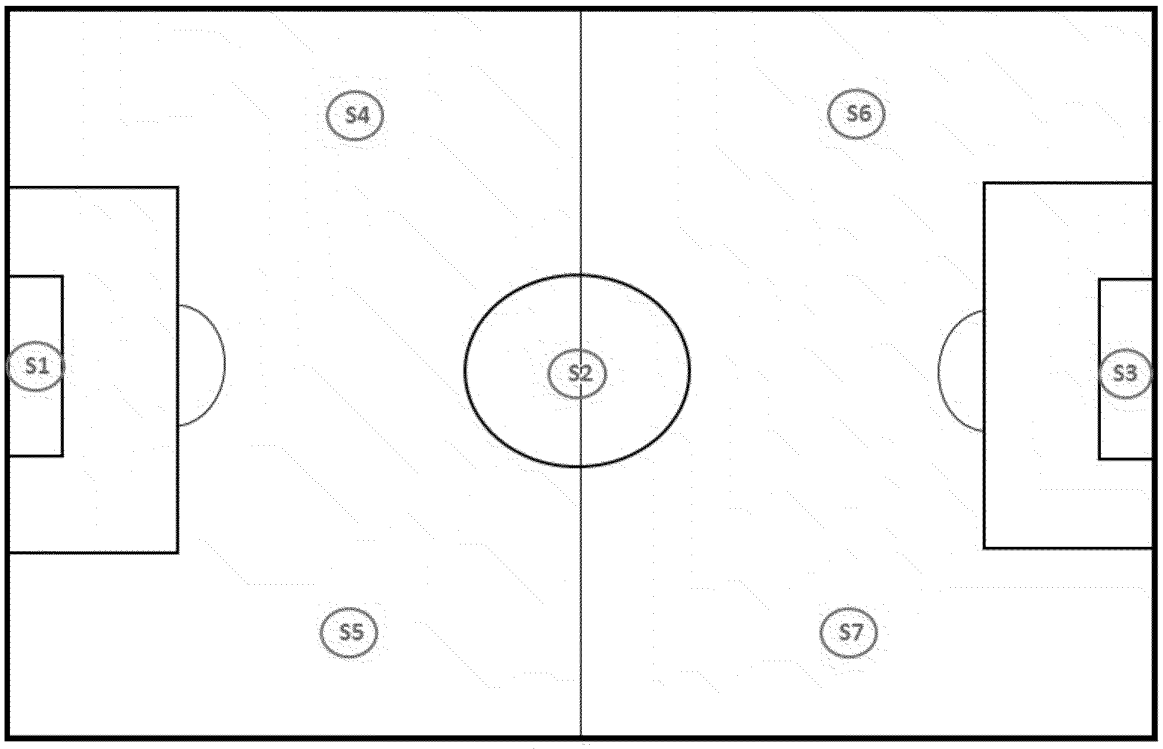
Dust Sample Collection – For Metals (Plastic Container)
(fill in collection location)

Field Location	Sample Collected
S__	Yes No

Dust Sample Collection – For Organics (Glass Container)
(fill in collection location)

Field Location	Sample Collected
S__	Yes No

Sample Collection Locations



SX = Sample Collection Locations

Form Approved
OMB No. 0923-XXXX
Exp. Date xx/xx/20xx
xxxxxx/xx/xx/20xx

Attachment 5c. Facility User Eligibility Screening

Caller: May I speak to [NAME OF Facility User]? A few weeks ago, you should have received a recruitment letter describing a new study on persons who participate in activities conducted on synthetic turf fields with crumb rubber infill. I am _____ from the Agency for Toxic Substances and Disease Registry (ATSDR), and I am calling you to determine your willingness to participate in this federally funded study being conducted with the United States Environmental Protection Agency (U.S. EPA).
Are you interested in participating in a short 5 minute survey to find out if you (your child) can participate in this project?

Facility user is not interested in the project:
Facility User: No, I am not interested at this time.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Facility user is interested in the project:
Facility user: Yes, I would like to learn more.
Caller: To find out if you are eligible, I will read the questions to you over the phone. If you are ready I'm going to read you a few questions.

If respondent is an adult, ask question #1. If respondent is a child, skip question #1 and go straight to question #2:

1. What is your age?....._____

If greater than 18 years of age, go to question #4.

If respondent is the parent/guardian of a child:

2. What is your child's age?....._____
   If the child is less than 6 years old, the respondent is not eligible to participate.
   Caller: As your child is not at least six years old, you are not eligible to participate in this project. I am sorry. Thank you for your time.
   END CALL.

   If child is 6 years or older:
3. What is your child's grade in school? ..... _____

For respondents greater than 18 years of age and respondents that are parents/guardians of children at least six years of age:

4. Did you (did your child) participate in activities on a synthetic turf field with crumb rubber infill during the previous year? ..... ☐

If no, respondent is not eligible to participate.
Caller: You are not eligible to participate in this project. I am sorry. Thank you for your time.
END CALL.

If yes, the following questions will be used to determine eligibility:

5. During the previous year, how many months did you (*did your child*) participate in activities on synthetic turf with crumb rubber infill? ..... _____

6. On average, how many days per week did you (did your child) practice or play football as part of an organized team on outdoor synthetic turf fields with crumb rubber infill? ... _____
On indoor synthetic turf fields with crumb rubber infill?..... _____

7. On average, how many days per week did you (did your child) practice or play soccer as part of an organized team on outdoor synthetic turf fields with crumb rubber infill? ..... _____
On indoor synthetic turf fields with crumb rubber infill?..... _____

8. On average, how many days per week did you (did your child) participate in physical training, physical education classes, or general recreation use on outdoor synthetic turf fields with crumb rubber infill? ..... _____
On indoor synthetic turf fields with crumb rubber infill?..... _____

9. Would you (would your child) be willing to complete a short survey to collect information about your time and activities that might affect exposures to chemical and microbiological agents associated with synthetic turf fields?..... ☐

10. Would you (would your child) be willing to be recorded on video during a sports practice or play activity on a synthetic turf field with crumb rubber infill? The video would be used to collection information about how people contact the fields and field materials that might affect exposures to chemical and microbiological agents. Yes..... ☐
No..... ☐
Will Not Have Eligible Activity in Study Time Frame ..... ☐

11. In addition to the survey, would you (would your child) be willing to participate in a study that measures potential chemical exposures while participating in an activity on a synthetic turf field with crumb rubber infill? This may include collecting a personal air sample, dermal wipe and cotton garment samples, and urine samples around a normal period of your (*his or her*) activity on a synthetic turf field. Air, wipe, and dust samples would be collected around the field during the activity area as well. Yes..... ☐
No..... ☐

Will Not Have Eligible Activity in Study Time Frame .....☐

The answers from the above questions will be used to determine eligibility at a later time.

Caller: Thank you for answering my questions today. We will use the information you have provided to determine whether or not you (your child) meet the requirements to participate in the study. If you (your child) is determined to be eligible, may I contact you in the future for participation in our study?
Facility user is not interested in participating:
Caller: Thank you for your time.
END CALL.

If facility user is willing to participate:
Caller: Thank you for your willingness to participate. I will call you at a later date to notify you of your eligibility and to schedule an appointment time. If you have any questions in the meantime, please feel free to contact me at xxx-xxx-xxxx.
END CALL.

Form Approved
OMB No. 0923-XXXX
Exp. Date xx/xx/20xx
xxxxxx/xx/xx/20xx

Attachment 5f. Full Exposure Characterization Form
[NOTE: tentative pending on study design completion and method availability]

Study ID Number _____

Sample Collection Date _____

Collector ID _____

Field Air Samples
(mark collection locations on field chart)

Sample Type	Field Location A Sample Collected		Field Location B Sample Collected		Background Location Sample Collected	
VOC Sample	Yes	No	Yes	No	Yes	No
SVOC Sample	Yes	No	Yes	No	Yes	No
Particle Sample	Yes	No	Yes	No	Yes	No

Field Wipe Samples
(mark collection locations on field chart)

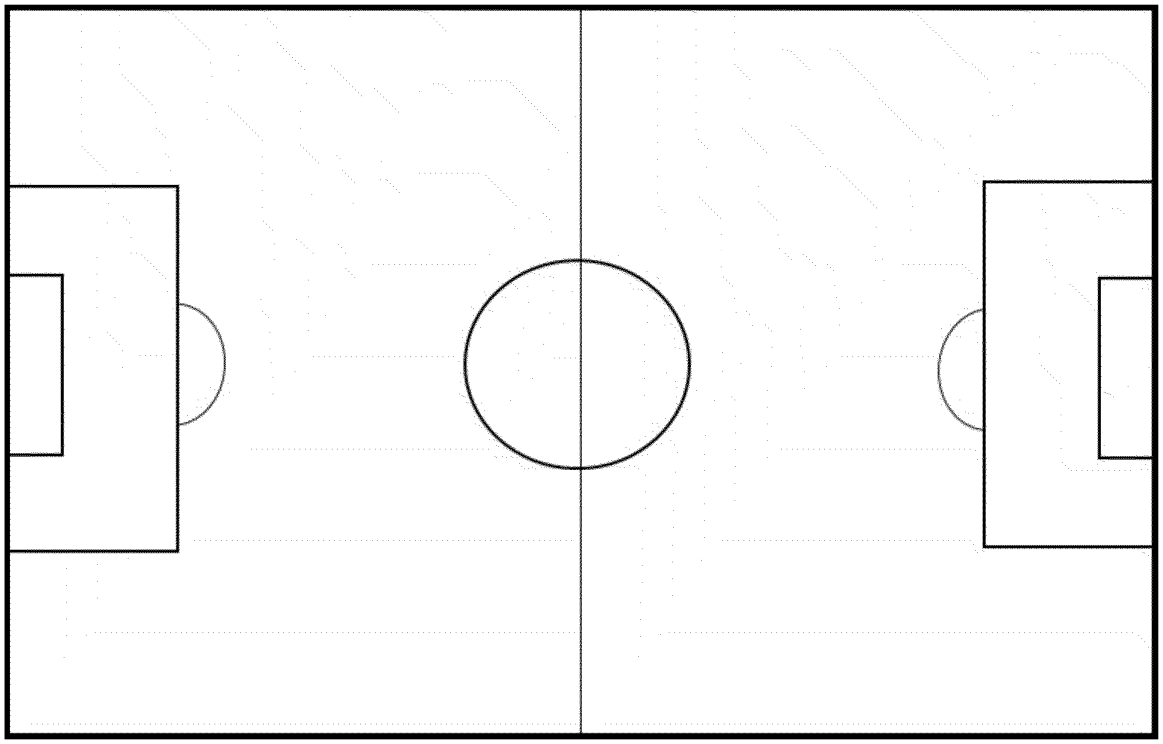
Sample Type	Field Location A Sample Collected		Field Location B Sample Collected		Field Location C Sample Collected	
SVOC Sample	Yes	No	Yes	No	Yes	No
Metals Sample	Yes	No	Yes	No	Yes	No

Field Dust Samples

(mark collection locations on field chart)

Sample Type	Field Location A Sample Collected		Field Location B Sample Collected		Field Location C Sample Collected	
SVOC Sample	Yes	No	Yes	No	Yes	No
Metals Sample	Yes	No	Yes	No	Yes	No

Sample Collection Locations



NOTE: Use one form for each participant if multiple participants are part of a sampling event

Study ID Number _____

Personal Air Sample – VOCs/SVOCs

Sample Type	Sample Collected	
Personal	Yes	No

Dermal Dosimeter Samples - SVOCs

Sample Type	Sample Collected	
Location 1	Yes	No
Location 2	Yes	No
Location 3	Yes	No
Location 4	Yes	No

Dermal Dosimeter Samples - Metals

Sample Type	Sample Collected	
Location 1	Yes	No
Location 2	Yes	No
Location 3	Yes	No
Location 4	Yes	No

Hand Wipe Sample - SVOCs

Sample Type	Sample Collected	
Hand 1	Yes	No

Hand Wipe Sample - Metals

Sample Type	Sample Collected	
Hand 2	Yes	No

Urine Samples Sample

Sample Type	Sample Collected

Pre-Activity	Yes	No
Post-Activity	Yes	No

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

OMB Control No. 0923-New

New Information Collection Request

Supporting Statement Part A –

Justification

Program Official: Angela Ragin-Wilson
Title: Chief, Environmental Epidemiology Branch
Phone: 770-488-3807
Email: ARagin@cdc.gov
Fax: 770-488-1547

Date: February 24, 2016

Table of Contents

Part A. Justification

Goals of the two studies: Under the constrained timeline of the Federal Research Action Plan, the research study designs are not intended for nationwide statistical generalizations. The research goals are to evaluate and characterize: Study 1) the chemical composition and use of synthetic turf with crumb rubber infill, and Study 2) the exposure potential to constituents in crumb rubber infill.

Intended use of the resulting data: To inform future public health decisions by: 1) providing information on the chemical composition of crumb rubber infill, and 2) estimating the exposure potential for persons with contact to crumb rubber. The research studies are anticipated to substantially add to knowledge on the topic, fill key data gaps, and improve exposure characterization capabilities needed to inform further evaluation. By the end of 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time.

Methods to be used to collect: Collections will occur by: 1) enrolling facilities in four US census regions with approximately ten facilities per region, administering questionnaires, and collecting samples of synthetic turf fields with crumb rubber infill; and 2) enrolling facility users and administering questionnaires. Where time and resources allow, a full exposure characterization sub-study among a subset of facility users may involve environmental and material sampling, personal air monitoring, dermal sampling, and urine collection.

Respondents: Both studies will use a convenience sample of respondents: 1) Facilities, through owners and operators knowledgeable about activity patterns, field maintenance, and other procedures affecting exposure to potential chemicals of concern; and 2) facility users (e.g., athletes) who are persons with potential for high exposures to contaminants in synthetic turf. The study will potentially include substantially more fields and field users than any previous study in the United States and around the world.

How data will be analyzed: To the extent possible, data will be analyzed using non-parametric statistical methods. If possible, the data will be used for exposure modeling and to perform screening level exposure evaluations.

A.1. Circumstances Making the Collection of Information Necessary

This is a new information collection request (ICR) for the Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (U.S. EPA) for two studies titled: 1) "Determination of Field Operating Procedures, Use Conditions, and Chemical Composition of Crumb Rubber Infill in Synthetic Turf Fields" (hereafter, Study 1) and 2) "Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill" (hereafter, Study 2).

ATSDR will request Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) clearance for 12 months or less for each study, in accordance with the "Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds."

Background

Synthetic turf fields are used across the United States with more than 12,000 fields currently in use (Synthetic Turf Council, 2015). These fields are often made with rubber granules from recycled tire waste used as infill (referred to as crumb rubber). There are differences in the types of crumb rubber, including differences due to processing and coating (Gomes et al, 2010). To date, there has been no comprehensive evaluation of crumb rubber material as previous studies are limited, often due to small sample size.

To date approximately 30 peer-reviewed studies have been published on synthetic/artificial turf and crumb rubber infill. These studies span four main topic areas: product sampling and chemical composition studies, biomonitoring studies, bioavailability studies, and toxicological/*in vitro* studies. However, the majority of the studies are limited in scope and in sample size. While the majority of studies identified numerous chemical compounds within the crumb rubber, including volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), and metals, the measured concentrations were generally low (Bocca et al, 2009; Ginsberg et al, 2011; Simcox et al, 2011; Kim et al, 2012; Marsili et al, 2014). One exception is zinc, which was found at high levels in most of the samples tested (Bocca et al, 2009; Kim et al, 2012; Marsili et al, 2014). However, chemical composition variability may be high even among rubber granules from the same origin (Menichini et al, 2011).

Limited data are available on the bioavailability of crumb rubber infill and the biomonitoring of persons exposed to crumb rubber infill. These studies are limited by laboratory methodology for stimulated gastric fluids and by small sample size and large inter-individual variation. However, the studies indicated that the rubber granules had low bioaccessibility for PAHs, but

lead was highly bioaccessible in the gastric fluid (Zhang et al, 2008; Kim et al 2012). However, previous work has shown that tire crumb samples with the highest total extractable lead content had the lowest bioaccessibility values for lead (EPA, 2009). The biomonitoring study measured only one PAH, 1-hydroxypyrene, in seven football players. While the study showed that uptake of PAHs by the participants was minimal, the sample size was very small and likely did not represent the target population. There have been anecdotal reports of cancer clusters in athletes and other deleterious effects from contact with crumb rubber infill (ESPN E:60). To date, the studies have not shown elevated health risks from use of and contact with synthetic turf. However, the studies are limited and do not comprehensively address the concerns about the potential health risks associated with exposure to chemicals in the crumb rubber infill.

In recent months, the public has raised concerns about the use and safety of synthetic turf with crumb rubber infill. In November 2015, the White House Council on Environmental Quality, requested that the Centers for Disease Control and Prevention (CDC)/ATSDR and the USEPA, in collaboration with the Consumer Product Safety Commission (CPSC), develop a Federal Research Action Plan to address the issues surrounding synthetic turf with crumb rubber infill. Part of the activities within the February 2016 plan, titled "Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds," will be led and implemented by the U.S. EPA and the CDC-National Center for Environmental Health (NCEH)/ATSDR, in collaboration with the CPSC and other agencies. The U.S. EPA/ATSDR activities related to the Federal Research Action Plan will seek to fill in important data gaps, specifically with respect to specific exposures to chemicals in the crumb rubber. The specific objectives for the one-year effort are to: 1) determine key knowledge gaps; 2) identify and characterize constituents of recycled tires used in artificial turf fields; 3) characterize exposures to potentially harmful constituents; 4) identify follow-up activities that could be conducted to provide additional insights about potential risks. By the end of 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time.

While the majority of the proposed activities can be carried out without seeking OMB approval, there are two proposed activities that require PRA clearance. These two specific activities are the subject of this ICR and are described below.

ATSDR is authorized by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)(1)(E), (7), (9), (15) and 9626(a)] to collect this study data (Attachment 1). The 60-day Federal Register Notice of the proposed information collection (IC) was published on February 18, 2016 (Attachment 2) and is further discussed in Section A.8.

A.2. Purpose and Use of the Information Collection

The purpose of this information collection is research to evaluate and characterize the chemical composition and use of synthetic turf with crumb rubber infill and exposure potential to contaminants in crumb rubber infill made with recycled tires. ATSDR, along with U.S. EPA, will implement two study protocols to collect this data. The data will be used to inform public health policy decisions and to guide future research activities.

A.2.1. Study 1 - Facility Information and Crumb Rubber Collection

In the first study, we will evaluate the manufacturing process and material use patterns to describe the tire crumb manufacturing process, the diversity of the processes, the variability of material blends, and the chemical constituents within the material. The ATSDR will work with its regional representatives to contact synthetic turf facility owners and operators. Outreach to multiple entities will be conducted, including but not limited to state partners, professional athlete organizations, or contacts within the Department of Defense or specific military branches. Additionally, individual municipalities may be contacted directly. For willing participants, we will invite them to participate (Attachment 4a and 4b), determine their eligibility and obtain their agreement to participate (Attachment 4d) and characterize field use patterns and field maintenance procedures using a structured questionnaire (Attachment 4e). Additionally, facility owners will be asked to provide samples from each field in order to obtain a better understanding of operating fields based on diverse conditions (Attachment 4f). The samples will be used to characterize chemical and possibly microbial constituents in a variety of crumb rubber infill material, including materials of different ages and weathering patterns. The samples will also be used to conduct laboratory bioavailability testing to determine bioaccessibility of samples using simulated bodily fluids, including but not limited to gastric fluids and saliva. Specifically, the first study will be conducted to identify key constituents of concern in crumb rubber infill in synthetic turf fields and possibly to evaluate potential cancer and non-cancer toxicity of key constituents using extant toxicity information.

A.2.2. Study 2 - Facility User Exposure Characterization

The second study will focus on exposure patterns in persons who are thought to have the potential for high exposure to chemical contaminants in crumb rubber infill, specifically adults and youth that routinely use synthetic turf fields with crumb rubber infill. Respondents will be categorized into specific age/activity groups, such as youth ages 6-8, youth ages 10-12, high school athletes or physical education, college athletes, and professional athletes. Invitations will be sent to prospective respondents (Attachment 5a and 5b). Interested facility users will be

screened for eligibility (Attachment 5c). The respondents will be asked to consent (Attachment 5d) and to answer a detailed questionnaire to determine activities associated with the use of synthetic turf with crumb rubber infill and related exposure factors (Attachment 5e). Extant video of people engaged in the activities of interest on synthetic turf fields with crumb rubber infill will be used for characterization of exposure scenarios.

If time and resources allow, we will conduct a more detailed full exposure characterization sub-study on a sub-sample of respondents. We will attempt to conduct the exposure characterization study at the same facilities used in the first study. The sub-study may include, but is not limited to, field environment and material sampling, personal air monitoring, dermal sampling, and urine collection. It is likely that some of the collection items will not be analyzed in the current project time frame but will be archived for future analysis. This information will be used to characterize exposure patterns and activities related to exposure to chemicals in crumb rubber infill. The second study will be conducted to include an assessment of potential exposures to potentially harmful constituents. This information will be used to inform educational materials for the public on best practices for minimizing exposure to potential constituents of concern in crumb rubber infill.

Both activities will be conducted on a one-time basis. The data will be analyzed by scientists at ATSDR and U.S. EPA and other federal partners to answer key questions related to crumb rubber infill in synthetic turf. There are specific limitations within each study. The limitations could include low sample size and low variability in age and weathering of field samples which could lead to lack of detailed chemical composition data and exposure misclassification. However, we feel that the activities set forth in each study will allow for evaluation of chemical constituents in crumb rubber infill and for characterization of exposure patterns for individuals with high exposure potential. The information gained from these studies will be used for education and communication and, if applicable, mitigation and prevention of exposure to contaminants in synthetic turf with crumb rubber infill.

A.3. Use of Improved Information Technology and Burden Reduction

To the extent possible, ATSDR and U.S. EPA plan to use electronic reporting in the form of computer assisted personal interviews (CAPIs) for data collection. However, the feasibility of using the electronic reporting remains to be determined for both protocol designs, as there is limited time to complete the collections. We anticipate the eligibility screening will also occur electronically prior to the questionnaires for both the facility owners and operators and for the facility users. The questionnaires will be administered by trained study interviewers. The questionnaires will incorporate computer-generated skip patterns thus alleviating respondent burden for inapplicable questions.

Additionally, we will use extant videography of persons engaged in activities of interest to characterize differing exposure scenarios. This technology will reduce respondent burden and improve data quality by allowing the investigators to accurately transmit video recording to objective measures of activities, rather than relying on self-reporting via questionnaires, which may be prone to bias.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ICR describes a joint effort between the U.S. EPA and ATSDR, in collaboration with the CPSC, to conduct two studies. CPSC has indicated its own plans to conduct a limited study of playground material with recycled tire material. However, as our studies do not incorporate playground material, there will be no duplication of efforts. Playground use and activity information, if collected by CPSC, may be useful for exposure modeling as a follow-on activity to exposure modeling for synthetic turf field users.

There are other studies currently being conducted, primarily by the California Office of Environmental Health and Hazard Assessment (OEHHA) and the Washington State Department of Health. While there could be slight duplication of efforts with the California OEHHA activities, their activities are limited to the state of California. The data collection described in this ICR will target four US census regions and will not focus on one state alone. We will work with California OEHHA to determine the feasibility of collecting some or all data in ways that promote comparability. The Washington State Department of Health's efforts are focused on a cancer incidence study among soccer players residing in the state at the time of diagnosis. However, the cancer incidence study is not designed to determine excess risk of cancer endpoints.

Prior to study initiation, outreach and engagement efforts may be undertaken among stakeholders, including but not limited to industry representatives, state representatives, and sports coaches. These efforts will inform the design of the proposed studies, and will involve less than ten respondents per stakeholder group. The outreach and engagement efforts will allow us to better understand the manufacturing process for synthetic turf and crumb rubber infill and will allow us to obtain first-hand perspectives on activities conducted on synthetic turf leading to potential exposures. ATSDR and U.S. EPA will use this opportunity to assess whether duplicate information of interest already exists, and needn't be included in the collections for either study.

Other attempts at identifying activities that could results in duplication of efforts, including literature searches, attendance at national meetings, and consultations with other federal and state agencies, did not reveal any other ongoing activities related to crumb rubber infill in

synthetic turf.

A.5. Impact on Small Businesses or Other Small Entities

The questions posed to small businesses, if applicable in either study, will be held to the absolute minimum required for the intended uses of the requested information.

A.5.1. Study 1 - Facility Information and Crumb Rubber Collection

The first study will involve facilities which may be defined as small businesses or small entities.[1] The estimated burden hours for this collection (n=76 hours) represents 26 percent of the total estimated burden hours for both studies (n=292 hours), as described in Section A.12.

A.5.2. Study 2 - Facility User Exposure Characterization

The second study will involve facility users which will likely not involve small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

Each study will be a one-time collection in accordance with the "Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds," and the respondents will respond once per form. If the collections are not conducted, the lack of knowledge regarding chemical constituents of crumb rubber infill and exposure potential to chemicals in crumb rubber infill will persist and responsive and actionable public health recommendations cannot be implemented.

There are no technical or legal obstacles to reducing burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Pending final protocol design for both studies, the following special circumstance(s) may apply

[1] Definition from OMB Form 83 I accessed 01/23/2016: A small entity may be (1) a small business which is deemed to be one that is independently owned and operated and that is not dominant in its field of operation; (2) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; or (3) a small government jurisdiction which is a government of a city, county, town, township, school district, or special district with a population of less than 50,000.

to these information collections.

1) We may ask the respondents in Study 1 (facilities) to submit proprietary trade secrets, or other confidential information.
2) Due to the time constraints of the Federal Research Action Plan, the respondents for the two studies will be a convenience sample; therefore, the results are not intended to be generalized to the universe of study. Previous studies have shown that there has been significant issues with obtaining permission to study and sample synthetic turf fields with crumb rubber infill. ATSDR and U.S. EPA are currently working to define the specifics of the field selection methods.

When the ICR for each study is submitted for PRA clearance, the protocols will have these elements fully described and justified, if necessary.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on February 18, 2016, Vol. 81, No. 32, pp. 8201-8202 (Attachment 2). If ATSDR and U.S. EPA receive substantive public comments related to this notice, the agencies will provide their response in Attachment 2a for the forthcoming ICRs.

   ATSDR and U.S. EPA have consulted directly with the White House Council of Environmental Quality and CPSC to obtain their views on the public health issue/concern surrounding crumb rubber infill in synthetic turf. The federal partners have drafted the "Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds." The activities outlined in the action plan are described in this information collection request.

Table A.8. 2016 ATSDR External Consultations

Name	Title	Affiliation	Phone	Email
FEDERAL CONSULTANTS				
Kent Thomas, BSPH	Research Physical Scientist	U.S. EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*
Annette Guiseppi-Elie, PhD	Associate Director for Exposure Science	U.S. EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*

Table A.8.2. 2016 Consultations with CDC NCEH Laboratories

Name	Title	Affiliation	Phone	Email
David Chambers, PhD	Lab Chief	Tobacco and Volatiles Branch	*(770) 488-0185*	*mzz7@cdc.gov*

A.9. Explanation of Any Payment or Gift to Respondents

A.9.1. Study 1 - Facility Information and Crumb Rubber Collection

Currently, there are no plans for providing incentives or any payment to facility respondents.

A.9.2. Study 2 - Facility User Exposure Characterization

For the study of activity levels among persons playing on synthetic turf with crumb rubber infill, it is likely that incremental tokens of appreciation in the form of gift cards will be provided to maximize the agencies' ability to recruit respondents. Eligible respondents who provide informed consent and who complete the activity questionnaire will receive a gift card (amount to be determined) as a token of thanks upon completion of the activities.

If a sub-sample of respondents undergo the full exposure characterization sub-study, these individuals will receive an additional gift card (amount also to be determined) for the monitoring and urine collection.

The gift cards for the second study will be offered at a total monetary level that is commensurate with previously approved collections (i.e., maximum of $75 for completion of both increments).

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

When the data collections for the two studies are fully designed, each will have a Privacy Act determination and information technology (IT) security review by the NCEH Information System Security Officer (ISSO).

A.10.1. Study 1 - Facility Information and Crumb Rubber Collection

Although the Privacy Act does not apply to organizations, some confidentiality statutes do apply to organizations, including those that protect confidential business information. The forthcoming ICR will describe:

- If the identity of the person(s) responding on behalf of the organization (may/may not)

be known.
- Any circumstances in which CDC/ATSDR requests information from an individual (particularly a named individual) on the basis of his or her role.
- Plans to protect sensitive information collected by or about organizations, under the appropriate statutory authority or authorities.

A.10.2. Study 2 - Facility User Exposure Characterization

If information in identifiable form (IIF) is collected from individual respondents, the Privacy Act will apply and the applicable IIF categories will be specified in the ICR for the forthcoming study. The applicable Privacy Act System of Records Notices (SORNs) will be ATSDR No. 09-19-0001 "Record of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances" (retrievable by name or SSN), CDC No. 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" (retrievable by name and ID number), and U.S. EPA No. EPA-34 "Medical and Research Study Records of Human Volunteers" (retrievable by name and ID number).[2]

The SORNs describe the privacy protections that must be in place to secure the information. Protocol details will be more fully described in the forthcoming ICR. The records will follow the required disposition schedules under: 1) CDC/ATSDR Records Control Schedule; and 2) EPA Records Schedule 566.

All privacy protections will be in place and assurance that all applicable privacy act requirements will be adhered to, to the extent allowable by law.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

If applicable, the two study protocols will be submitted to the CDC IRB for human subjects review. Following IRB approval, the protocol and IRB documentation will be submitted to the U.S. EPA Human Subjects Research Review Official for review and approval. All human subjects protections will be implemented.

ATSDR and U.S. EPA intend to collect the minimum amount of sensitive information necessary to meet the objectives of the two studies. Some of the information could be viewed as sensitive by the respondents, specifically related to field procedures, videotaping, etc. All respondents will be consented and informed that their participation is voluntary, that they will not be named in any publications, and that they can choose to not answer any question.

[2] SORNS accessed 01/21/2016
1) ATSDR No. 09-19-0001 - Federal Register: January 25, 2011 (Volume 76, Number 16, Page 4432-4435)
2) CDC No. 09-20-0136 - Federal Register: January 25, 2011 (Volume 76, Number 16, Page 4458-4460)
3) EPA 34 - Federal Register: February 22, 2002 (Volume 67, Number 36, Page 8259-8260)

A.12. Estimates of Annualized Burden Hours and Costs

The agencies' burden estimates were based on early conversations with the CPSC and the White House Council on Environmental Quality. The total estimated time burden for the two studies to be conducted under "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" is 292 hours. Estimated annualized burden hours are presented for each study below.

A.12.1. Study 1 - Facility Information and Crumb Rubber Collection

The estimated burden hours for the study titled "Determination of Field Operating Procedures, Use Conditions, and Chemical Composition of Crumb Rubber Infill in Synthetic Turf Fields" is 76 hours.

- Identified facility owners/operators will be mailed an introduction letter with information on the study. The facility owners/operators will also be contacted via telephone to determine interest in study participation and to determine eligibility. The eligibility screening survey is estimated to take 5 minutes results in a burden of 6 hours.
- For the estimated time burdens for the facility owners/operators, the questionnaire detailing standard operating procedures for synthetic turf fields is estimated to take 45 minutes resulting in a burden of 30 hours.

Table A.12.1a: Estimated burden hours for Study 1

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Facilities	Facilities Eligibility Screening	70	1	5/60	6
	Synthetic Turf Fields Questionnaire	40	1	45/60	30
	Field Sampling Collection	40	1	1	40
Total					76

For the facilities personnel, to estimate the cost of the respondent, the median hourly wage for turf managers was determined using a document provided by Rutgers University (http://turf-management-jobs.rutgers.edu/turf-management-salary.html).

Table A.12.1.b: Estimated annualized burden costs for Study 1

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Facilities	Facilities Eligibility Screening	6	$45.00	$270.00
	Synthetic Turf Fields Questionnaire	30	$45.00	$1,350.00
	Field Sampling Collection	40	$45.00	$1,800.00
Total				$3,420.00

A.12.2. Study 2 - Facility User Exposure Characterization

For the respondents in the facility user exposure characterization, the eligibility screening is estimated to take 5 minutes resulting in a burden of 6 hours. For the activity questionnaire, we estimate the respondent burden to be 30 hours, based on 60 respondents at 30 minutes.

A sub-sample of the respondents will participate in a full exposure characterization, including personal monitoring and urine collection, resulting in a burden of 180 hours.

Table A.12.2.a: Estimated burden hours for Study 2

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Facility Users	Facility User Eligibility Screening	75	1	5/60	6
	Facility User Questionnaire	60	1	30/60	30

	Exposure Characterization Sampling Collection Form	45	1	4	180
Total					216

For the second study respondent cohort, the facility users are assumed to be college student athletes with an earning potential, if employed, of $7.25/hour based on federal minimum wage. See http://www.dol.gov/general/topic/wages/minimumwage.

Table A.12.2.b: Estimated annualized burden costs for Study 2

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Facility Users	Facility User Eligibility Screening	6	$7.25	$43.50
	Activity Questionnaire	30	$7.25	$217.50
	Exposure Characterization Sampling Collection Form	180	$7.25	$1,305.00
Total				$1,566.00

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no additional capital and maintenance costs for the two studies described in this ICR, "Collection Related to Synthetic Turf with Crumb Rubber Infill," for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

For these two collections, the annual personnel costs are based on a FTE at GS-13/1 with an

estimated 12 full time staff. The estimated average annualized cost of the program is $1,079,660.

- Personnel: $1,059,660 per year.
- Travel: $20,000. This amount is based on the number of site visits conducted.

Other project requirements, including but not limited to, laboratory analysis, bioavailability studies, and hazard assessments, are estimated to cost $1.80 million. In total, the estimated annual cost to the government is $2.88 million, based on the estimated costs in the Federal Research Action Plan.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Information collections will begin at the time of OMB approval. Upon completion of data collection and laboratory analysis, ATSDR and U.S. EPA may report on the various activities to the respondents (Attachment 4g and 5g) and to the public. Specifically, by the end of November 2016, the agencies will release a draft report that describes the findings and conclusions of the work conducted under this approval and other activities in the Federal Research Action Plan through that point in time. The report will help answer some of the key questions that have been raised about tire crumb used in artificial turf fields, and will provide a better understanding of potential exposures that athletes and others may experience by using these fields. For more details, see Table A.16.

Table A.16: Timeline for Activities Investigating Crumb Rubber Infill in Synthetic Turf

Activity	2015 - 2016								
	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Au
Task 1: Federal agency engagement and coordination	X	X	X	X	X	X	X	X	X
Task 2: Conduct outreach with stakeholders and states		X	X	X	X	X			
Task 3: Literature review and key science gap analysis	X	X							
Prepare for research									
Peer-reviewed study design	X	X	X	X					
Quality assurance project plan		X	X	X					
Contracts issuance		X	X	X					
Human subjects approvals			X	X					
OMB ICR approval	X	X	X	X					
NOTE: Some of the activities in Tasks 4 and 5 require finalized study design, humans subjects approval, and OMB IC									
Task 4: Characterize constituents, emissions, and bioavailability									
a. Evaluate information on tire crumb material		X	X	X	X				
b. Laboratory constituent characterization					X	X	X	X	X
c. Laboratory bioavailability assessment						X	X	X	X
d. Obtain extant toxicity information on constituents							X	X	X
Task 5: Characterize exposure under use conditions									
a. Characterize exposure scenarios and activity patterns		X	X	X	X	X	X	X	X
b. Conduct pilot scale exposure characterization study					X	X	X	X	X
c. Develop methods for measuring exposures		X	X	X	X				
Research report									

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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List of Attachments

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

OMB Control No. 0923-New

New Information Collection Request

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

Program Official: Angela Ragin-Wilson
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Date: February 24, 2016

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (U.S. EPA) have consulted directly with the White House Council of Environmental Quality and the Consumer Product Safety Council (CPSC) to obtain their views on the public health issue/concern surrounding crumb rubber infill in synthetic turf. These federal partners have drafted the "Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds."

As part of the Federal Research Action Plan, this is a new Information Collection Request (ICR) for two studies sponsored by ATSDR and U.S. EPA. The first is aimed at obtaining information about synthetic turf field facilities and operations, along with collection of recycled tire crumb rubber infill samples and possibly dust samples for chemical constituent analyses. Crumb rubber infill samples may also be collected for microbial analyses. The second study is a pilot-scale effort aimed at obtaining facility user activity information and data, with a subset of respondents taking part in an exposure measurement study. The second study is intended to provide information for characterizing exposures for synthetic turf field use scenario(s) that are likely associated with higher exposures.

Important study design constraints include the mandated timeline for research activity completion and reporting under the Federal Research Action Plan, and the resources available for implementing the research. By the end of 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time. Therefore, a convenience sample will be used for both studies. Because the studies will not involve statistically-based sampling designs, the research will not provide data intended for nationwide generalizations. However, the research is anticipated to provide more information than is currently available, to fill key data gaps, and to improve exposure characterization capabilities needed to inform further evaluation. If successful, the study will also include more fields and field users than any previous single study in the U.S. and around the world.

B.1.1 Study 1 – Facility Information and Crumb Rubber Constituents

The respondents of interest are facilities with synthetic turf fields using recycled crumb rubber as an infill material. Synthetic turf fields are used across the United States with more than 12,000 fields currently in use (Synthetic Turf Council, 2015). Synthetic turf fields are primarily installed at municipal and county parks, schools, stadiums, and military installations. They are typically used for athletic, recreation, and physical education and physical training activities, although some fields may see multi-purpose uses, such as concerts and ceremonies. While the

research will attempt to recruit participation from a diverse array of facility types in the four census regions of the U.S., the facilities will not be selected as a representative sample of all U.S facilities

B.1.1.2 Study 2 – Exposure Characterization

The respondents of interest are adults and youth that routinely use synthetic turf fields with crumb rubber infill for athletics, recreation, and/or physical education or physical training purposes (examples of age groups and activities of interest are provided in Table 8). No data are available regarding the numbers of such individuals in the United States, however, given the large number of installed fields it can be reasonably anticipated that the number of users is in the millions. As described in the Federal Research Action Plan, this research is a pilot-scale effort aimed at providing information and data for exposure characterization purposes. Respondents will be recruited from among those thought to be in one or more higher-exposure scenarios based on the frequency and duration of synthetic turf field use, as well as specific activities that may be involved in higher levels of contact with crumb rubber material. We anticipate that the facilities used by the Study 2 respondents will be a subset of the facilities participating in Study 1.

B.2. Procedures for the Collection of Information

B.2.1 Study 1 – Facility Information and Crumb Rubber Constituents Research Aims

There are two primary aims of Study 1. First, there are important data gaps about how synthetic turf fields with crumb rubber infill are operated, maintained, and used with regard to characteristics potentially impacting human exposure to crumb rubber constituents. Differences in source material, material age, indoor vs. outdoor installation, crumb addition or replacement frequencies, maintenance procedures (e.g. redistribution of crumb rubber material), facility operations (e.g. ventilation for indoor facilities), and other factors may affect exposures. This study is intended to collect information from a diverse array of facilities around the U.S. using questionnaires administered to facility owners/managers.

Second, there are some data gaps regarding the types and concentrations of the chemical constituents and contaminants in crumb rubber material and their potential availability for human exposure and internal dose. While a number of research studies have examined crumb rubber constituents, most studies have been small, restricted to a few fields or material sources, and measured a limited number of constituents and contaminants. Also, few studies have attempted to assess potential differences in crumb rubber constituents and human exposure potential across multiple factors including location (e.g. material source and weathering), material age, and facility type (e.g. outdoor vs. indoor). There are also gaps in our knowledge regarding microbial populations associated with crumb rubber on synthetic turf fields. This study is intended to collect crumb rubber infill material from a diverse array of

facilities around the U.S., with laboratory analysis for a wide range of metals, volatile organic compounds (VOCs), and semi-volatile organic compounds (SVOCs). Laboratory analyses will include bioavailability measurements for metals and SVOCs, and emission rate measurements for VOCs and SVOCs under different temperature conditions. In addition, non-targeted analysis methods will be applied for VOCs and SVOCs in an attempt to identify whether there may be potential chemicals of interest based on exposure potential and toxicity that have not been identified in previous research. Collection and analysis of field dust samples from synthetic fields with crumb rubber infill is also of interest as a potential exposure parameter; methodology for field dust collection will be examined and implemented if feasible. The study may also collect crumb rubber material to assess microbial populations. A final piece of this research activity is to collate available extant toxicity data for chemical constituents and contaminants identified through laboratory analysis.

B.2.1.1 Study 1 – Facility Information Collection

Up to 40 facilities with synthetic turf fields with crumb rubber infill will be recruited across the four U.S. census regions. The geographical diversity is likely to provide a range of material weathering conditions for outdoor fields and may include differences in crumb rubber source material. Additional stratification by crumb rubber material age (≤2 years old vs. ≥5years old) and facility type (indoor vs. outdoor) will be attempted at the facility identification and recruitment stage (Table 6). Additionally, samples of natural turf fields at the same facilities may be collected.

Table 6. Number and types of facilities/fields

U.S. Census Region	Outdoor Field ≤ 2 Years Old	Outdoor Field ≥ 5 Years Old	Indoor Field ≤ 2 Years Old	Indoor Field ≥ 5 Years Old	Total Number of Fields
Northeast	2	2	3	3	10
South	3	3	2	2	10
Midwest	2	2	3	3	10
West	3	3	2	2	10
Total Number of Fields	10	10	10	10	40

Multiple outreach mechanisms will be used to identify and recruit facilities. Federal contacts with state government organizations, including state departments of health may be used to identify state and local facilities, or as an intermediary for introduction to other state and local government organizations. The Department of Defense or specific military branches may be contacted for assessing interest in participation of facilities at military installations. Professional and college athletic organizations may be contacted. Individual institutions or municipalities may be contacted directly. Contacts will be made with facility owners/managers to determine their level of research participation interest, potential eligibility (facilities with fields in Table 6 categories), and availability during the research implementation time frame for answering a questionnaire and providing or allowing collection of crumb rubber material samples. Up to 70 facilities may be contacted for eligibility determination using a structured eligibility assessment screening form (Attachment 4c).

Facility owners/managers agreeing to participate will be administered a questionnaire (Attachment 4e) by trained research staff in-person or over the phone. The research staff member will make arrangements for providing a sample collection kit to a designated facility manager or staff member. The facility manager or staff member will collect crumb rubber material from multiple locations on the field, and will return the samples in sealed containers by overnight delivery service using packaging provided by research staff. Alternatively, federal and/or contractor staff will visit the facility to collect and ship samples. (At this time, options for sample collection by research staff and/or facility owners/managers are being considered). For most facilities, samples collected from seven pre-defined locations will be collected and composited in the laboratory (see the field sample collection form in Attachment 4f). At a subset of fields, three of the pre-defined location samples will also be analyzed for intra-field variability assessment. Samples will be received at a central laboratory facility where composite samples and aliquots will be prepared and distributed to analysis laboratories.

B.2.1.2 Study 1 –Crumb Rubber Infill Chemical Constituent Analysis

Crumb rubber material will be analyzed by laboratories for a wide range of volatile and semi-volatile organic (VOC and SVOC) and metals constituents and under a range of conditions related to assessing exposure potential. Samples will be analyzed for assessing bioavailability of selected metals and SVOCs. Samples will also be placed in emission chambers under controlled conditions of ventilation, temperature, and humidity. Emission rate measurements will be made for at least two temperature conditions, including a temperature that may represent a warm indoor facility (25°C) and an upper temperature that approaches what has been reported for synthetic field surfaces under the hottest ambient conditions (approximately 60°C). Emission rates will be measured for selected VOCs and SVOCs. Non-targeted chemical analysis techniques will also be applied to a subset of VOC and SVOC emission samples. Extant toxicological information will be compiled for crumb rubber chemical constituents of interest

identified through laboratory analyses to inform hazard identification.

Although the research is not being conducted under a statistically-based design, it is of interest to explore the potential statistical power for assessing differences in the facility groups described (Table 6) stratified by geographic location, or material age, or indoor vs. outdoor location. Measurement data for two chemicals of possible interest, lead and benzo(a)pyrene (BaP), were obtained from the literature. Using reported means and standard deviations, a range of powers for detecting significant differences in facility group means was calculated for sample sizes of 10 or 20 in each group (Table 7).

These estimates suggest that for measurements of chemicals in crumb rubber materials with relatively low variability (low coefficients of variation or CV) across different fields, differences in means below 50% for 10 fields in each group and below 20% for 20 fields in each group may be statistically significant. For chemicals with higher variability among fields, significant differences may only be found for differences in means above 100%. While larger samples sizes would be preferred, the proposed sample size offers the opportunity to assess whether there are likely to be important differences that may affect human exposure among facility location, crumb rubber age, and facility type.

Table 7. Power of the t-test to detect differences between two groups (α=0.05)

	N = 10/facility group		N = 20/facility group	
	Lead[a]	BaP[b]	Lead	BaP
	CV1 = 0.18	CV1 = 1.13	CV1 = 0.18	CV1 = 1.13
Difference	CV2 = 0.18	CV2 = 1.13	CV2 = 0.18	CV2 = 1.13
20%	0.645	0.066	0.925	0.085
50%	>0.99	0.156	>0.99	0.278
100%	>0.99	0.469	>0.99	0.782
200%	>0.99	0.964	>0.99	>0.99

[a] Lead measured in crumb rubber from 5 fields, mean 26.6 ± 4.1 µg/g; Highsmith R., Thomas K.W., Williams R.W. (2009). A Scoping-Level Field Monitoring Study of Synthetic Turf and Playgrounds; EPA/600/R-09/135. National Exposure Research Laboratory, U.S. Environmental Protection Agency.

[b] Benzo(a)pyrene measured in uncoated crumb rubber from four fields, mean 4.1 ± 4.5 µg/g ; Menichini et al. (2011). Artificial-turf Playing Fields: Contents of Metals, PAHs, PCBs, PCDDs and PCDFs, Inhalation Exposure to PAHs and Related Preliminary Risk Assessment. Sci Total Environ. 409(23):4950-7.

Beyond statistical tests of differences of data between groups, the proposed data collection across a diverse range of facilities in the U.S. will provide important information for

characterizing exposures to crumb rubber constituents:

a) facility installation and operation information and data,
b) the spectrum of user groups, activity types, use durations and frequencies,
c) the concentrations and bioavailability of selected crumb rubber chemical constituents,
d) emission rates of selected crumb rubber constituents under different conditions,
e) potential identification of crumb rubber constituents not previously measured or identified,
f) a listing of crumb rubber constituents found across all analyses, and,
g) toxicological information for identified crumb rubber constituents of interest.

The information and data will be made available for human exposure screening assessments and more detailed exposure modeling.

B.2.2. Study 2 – Exposure Characterization Research Aims

There are two primary aims of Study 2. First, there are important data gaps in human activity parameters for various synthetic turf field users that affect potential exposures to crumb rubber constituents. This study is intended to collect information using questionnaires from adults and youth who use synthetic turf fields with crumb rubber infill for several types of active uses including athletics and possibly physical education or physical training. Information will be collected to provide data about relevant parameters for characterizing and modeling exposures associated with the use of synthetic turf fields. In addition, extant videography of users engaged in activities on synthetic fields will, if feasible, be acquired to provide objective assessment of contact rates and types that are difficult to capture consistently using questionnaires.

Second, the human exposure measurement data for synthetic turf field users are limited. Important data gaps exist, particularly for potential dermal and ingestion exposures to crumb rubber constituents. There are also important limitations in the types of methods that have been developed and used for human exposure measurements during activities on synthetic fields. There are challenges in collecting relevant surface, dust, and personal air samples. Few studies have performed measurements of dermal exposures. And few studies have collected urine or blood samples that might be used for measuring biomarkers of exposures to chemicals in crumb rubber infill. As a pilot scale effort, this study will implement a human exposure measurement study to further develop and deploy appropriate sample collection methods and to generate data for improved exposure characterization. The study will be aimed at generating data for field use scenarios anticipated to be among those resulting in the highest potential for exposures.

B.2.2.1 Study 2 – Field User Information Collection

Up to 75 people who engage in physical activities at facilities with synthetic turf fields with crumb rubber infill will be recruited across several use-type categories (Table 8). The categories will include activity types anticipated to be among those resulting in higher exposure scenarios either because of the intensity and frequency of field use or because of potentially inherent differences in activity factors (e.g. children younger than age 12 that have higher hand-to-mouth contact rates). Examples of user types and categories and number of respondents of interest for data collection are shown in Table 8.

We anticipate that respondents will be recruited from users of a subset of facilities recruited for participation in Study 1. Multiple outreach mechanisms will be used to identify and recruit facility users. As part of the contact with facility owners and managers (identified and contacted as part of Study 1), the respondents will be asked whether they can assist in identifying and contacting organizations with members including potential respondents of interest. These may include professional team owners/managers, college athletics officials, secondary school officials, youth sport league officials, or other types of organizations. The Department of Defense or specific military branches may be contacted for assessing interest in participation by users of facilities at military installations. Individual organizations or officials may be contacted directly. Contacts will be made with organizational officials to determine their level of research participation interest, potential eligibility of facility users (e.g. users in Table 8 categories), and availability during the research implementation time frame for answering a questionnaire and participation in the exposure measurement activities (Section B.2.2.2).

Table 8. Number and types of facility users to be recruited for questionnaire data collection

	Questionnaires[b]			
Activity Type[a]	Indoor Facility	Outdoor Facility	Total Number Of Users	Total Number Of Facilities
Professional athletics	8	7	15	2
College athletics	8	7	15	2
High school P.E. or athletics	8	7	15	2
Youth 10 – 12 athletics	8	7	15	2
Youth 6 – 8 athletics	8	7	15	2
Total Number of Users			75	10

[a] These are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.

[b] It is anticipated that up to 60 of the 75 people recruited will participate. Up to two facilities for each type of activity; the facilities are likely to be different for each activity type.

We anticipate that respondents will be recruited from users of a subset of facilities recruited for participation in Study 1. As indicated above, multiple outreach mechanisms will be used to identify and recruit facility users. We anticipate recruiting respondents from only two different facilities for each type of activity to minimize the time and cost given the study constraints. Facility users will be contacted to determine eligibility (Attachment 5c) and request participation in the questionnaire and exposure measurement research activities (for a subset of questionnaire respondents). Based on *a priori* decisions regarding activities that may be among higher exposure scenarios, the recruitment may focus on specific types of users among a larger group. For example, more soccer goalies than field players may be recruited from a soccer team or league based on their likely higher contact rates with field materials. Facility users who agree to participate will be administered a questionnaire (Attachment 5e) by trained research staff in person or over the phone. The questionnaire will be used to collect Information about characteristics and activity parameters that may affect the magnitude of exposure to crumb rubber infill constituents, including:

a) demographic characteristics,
b) frequency of field use across a range of activity types,
c) duration of field use across a range of activity types,
d) levels of physical exertion that affect breathing rates,
e) contact rates for different types of activities,
f) different clothing types and uses, and,
g) hygiene practices.

If a videography component is included in this research, extant videography of physical activities on synthetic turf fields will be used. A range of activities, including those in team practices and in games may be considered for video information collection and analysis. Video data collection will include simple counts of specific activity types, including but not limited to hand-to-mouth, diving on turf, falling on turf, laying on turf, sitting on turf, and hand contact with turf. Information about clothing and protective equipment type and usage may also be collected.

Questionnaire and videographic-based data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although a statistical design is not being implemented, differences among user groups will be explored to assess whether differences in activity types, durations, and frequencies occur that may affect exposure to crumb rubber constituents. No data sets have been identified that can be used to inform between-group difference power calculations for the exposure scenario parameters of interest (e.g. mean and standard deviation values for hours of

field use per week, number of hand-to-field contacts per hour). There may be some autocorrelation in results because multiple people from a given facility and/or team will be included.

B.2.2.2 Study 2 – Field User Exposure Measurement Collection

Up to 45 people who engage in physical activities at facilities with synthetic turf fields with crumb rubber infill will be recruited across one to three use-type categories for participation in the exposure measurement portion of the research study. These respondents are anticipated to be a subset of those who respond to the questionnaire administration. The category or categories will include activity types expected to be among those resulting in higher exposure scenarios either because of the intensity and frequency of field use or because of potentially inherent differences in activity factors. Examples of user types and categories and number of respondents of interest for data collection are shown in Table 9.

Facilities where exposure measurements are made will also be considered respondents since facility-area samples will be collected.

Table 9. Number and types of facility users to be recruited for exposure measurements

Activity Type[a]	Indoor Facility[b]	Outdoor Facility[b]	Total Number of Users	Total Number of Facilities
Professional athletics	8	7	15	2
College athletics	8	7	15	2
Youth (ages 6 – 8) athletics	8	7	15	2
Total Number of Users			45	6

[a] These are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.

[b] It is assumed that all of the people recruited for questionnaire administration in selected activity categories will participate in the exposure measurement portion of the study. Up to two facilities for each type of activity; the facilities are likely to be different for each activity type.

Several types of personal and facility samples will be collected (Table 10). Specific sample collection and analysis methods have not been identified at this time. Some methods, including dust from synthetic turf fields, may require method development in advance of the conducting

the exposure measurement study. An exposure characterization sampling collection form is provided in Attachment 5f.

Table 10. Number and types of samples for exposure characterization measurements[a]

Sample Type	Number of Users	Number of Facilities[c]	Number of Locations or Samples	Analytes[d]	Total Samples or Analyses
Personal Samples					
Air	45		1	VOCs	45
Dermal	45		4	SVOCs, metals	360
Urine	45		2	SVOCs, metals	180
Facility Samples[b]					
Air		6	3[e]	VOCs, SVOCs, particulates	54
Surface wipe		6	3	SVOCs, metals	36
Dust		6	3	SVOCs, metals	36

[a]These are anticipated types and numbers of samples. Final decisions will be based on method availability, resources, respondent burden, and respondent safety considerations

[b]Samples of crumb rubber infill analyzed for constituents as part of Study 1.

[c]Includes one indoor and one outdoor facility for each activity type

[d]Each analyte type will require a separate sample

[e]Includes one-off field background location for each field.

Exposure measurement data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although a statistical design is not being implemented, differences among user groups will be explored to assess whether differences in activity and/or facility types result in differences in exposure to crumb rubber constituents. Estimation of population distributions of exposures will not be possible using these data; however, if the scenarios do represent those leading to higher exposures then the data will inform exposure assessment of what is likely to be in the upper end of the distribution.

Some samples collected as part of the exposure characterization Study 2 may not be analyzed within the time frame required for inclusion of results in the November 2016 report due to the research time constraints. For example, it is likely that the urine samples will not be analyzed during the mandated research time period. Also, while there are existing biomarker analysis

methods for many previously reported tire crumb constituents, the research performed in this study may identify additional constituents of interest or concern for which biomarker analysis methods are not available. If that is the case new biomarker analyte measurement methods may need to be developed, but that is beyond the scope of this research study.

B.3. Methods to Maximize Response Rates and Deal with No Response

Although this research does not rely on a statistically representative sample, a critical factor for the success of this study is identifying and recruiting a diverse range of facility and facility user respondents in a very short time frame. Immediately upon receiving approvals, we will contact numerous organizations and institutions to provide information about the purpose and value of the research and to request participation. We will employ a number of strategies in an attempt to maximize response rates. These include having trained study representatives: 1) make multiple phone calls/visits at different times of day and on different days of the week; 2) leave detailed messages with a call-back number; and 3) calling "alternate contacts." Key CDC/ATSDR and U.S. EPA leaders may be asked to make initial or follow-up contacts at appropriate organization and institution levels to facilitate engagement.

B.4. Test of Procedures or Methods to be Undertaken

Few of the procedures and methods to be used in this study have been previously tested and evaluated. Exceptions may be air (metals and particulates), surface (metals), and material (metals) sample collection and analysis procedures used in the 2008-2009 U.S. EPA Scoping Study (Highsmith et al., 2009).

Due to the very short timeline mandated for this research effort, any testing of survey instruments and measurement methods will be limited. However, any testing will occur among federal employees or among nine or fewer members of the public. ATSDR and U.S. EPA will complete testing and modifications prior to submitting the ICRs for PRA clearance if time does permit.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Table 11. Personnel Consulted on Statistical Design

Name	Title	Affiliation	Phone	Email
FEDERAL AGENCY				
Paul Jones, PhD	Biostatistician	U.S. EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*

Table 12. Personnel Responsible for Collection and Analysis of Information

Name	Title	Affiliation	Phone	Email
Kent Thomas, BSPH	Research Physical Scientist	U.S. EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*
Annette Guiseppi-Elie, PhD	Associate Director for Exposure Science	U.S. EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*
Angela Ragin-Wilson, PhD	Chief, Environmental Epidemiology Branch	CDC/ATSDR	*770-488-3807*	*ARagin@cdc.gov*
Elizabeth Irvin-Barnwell, PhD	Team Lead, Environmental Epidemiology Branch	CDC/ATSDR	*770-488-3684*	*Jcx0@cdc.gov*
Contractors TBD				

References

Highsmith R., Thomas K.W., Williams R.W. (2009). A Scoping-Level Field Monitoring Study of Synthetic Turf and Playgrounds; EPA/600/R-09/135. National Exposure Research Laboratory, U.S. Environmental Protection Agency. http://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=215113&simpleSearch=1&searchAll=EPA%2F600%2FR-09%2F135

Menichini et al. (2011). Artificial-turf Playing Fields: Contents of Metals, PAHs, PCBs, PCDDs and PCDFs, Inhalation Exposure to PAHs and Related Preliminary Risk Assessment. Sci Total Environ. 409(23):4950-7.

List of Attachments